

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fine et al.

Serial No: 09/787,325

Filed: June 4, 2001

For: Combinations of Chromium or
Vanadium with Antidiabetics for
Glucose Metabolism Diseases

Examiner: Criares, T.

Art Unit: 1617

Attorney Docket No. AKT-053.02

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CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date

John Barretto

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97 (c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449.

This Information Disclosure Statement is being submitted after the events recited in 37 C.F.R. § 1.97 (b). The Commissioner is therefore authorized to charge the fee set forth in § 1.17 (p) to our **Deposit Account No. 06-1448, reference AKT-053.02.**

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form. Documents A1 through A3 were not previously cited, and full copies of such documents are provided herewith. Applicants note that Documents C1 through C11 have been previously cited.

The present Supplemental Information Disclosure Statement simply provides information about Documents C1 through C11, such as a date or more complete citation, that Examiner noted was missing in the Office Action mailed June 2, 2003. No copies of Documents C1 through C11 have been provided.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

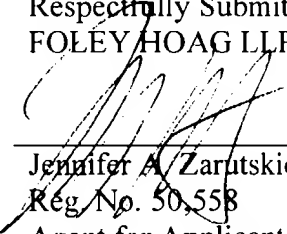
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there are any additional fees due in connection with this submission, the Commissioner is authorized to charge any deficiencies or credit any overpayment to/from our **Deposit Account No. 06-1448, reference AKT-053.02**

Date: December 3, 2003

Customer No: 25181
Patent Group
Foley Hoag LLP
155 Seaport Blvd.
Boston, MA 02210-2600
Phone: (617) 832-1000
Fax: (617) 832-7000

Respectfully Submitted,
FOLEY HOAG LLP



Jennifer A. Zarutskie, Ph.D.
Reg. No. 50,558
Agent for Applicants

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number (Optional)

AKT-053.02

Application Number

09/787,325

Applicant

Stuart A. Fine et al.

Filing Date

September 17, 1999

Group Art Unit

1617

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---------------------|-----------------|-----------|------------|------------|-------|----------|-------------------------------|
| | A1 | 5,962,030 | 10/05/1999 | Fine | 424 | 646 | 11/05/1997 |
| | A2 | 6,203,819 | 03/20/2001 | Fine | 424 | 646 | 03/19/1999 |
| | A3 | 6,376,549 | 04/23/2003 | Fine et al | 514 | 635 | 09/17/1998 |

FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | Translation YES NO |
|-----------------|------|---------|-------|----------|-----------------------|
|-----------------|------|---------|-------|----------|-----------------------|

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages Etc.)

| | |
|-----|---|
| C1 | "Chromium picolinate for good health?," Biolifeplus.com, 'Online! 10/16/99, XP002135607, www.biolifeplus.com/library/chromium.html , retrieved on 4/5/00 |
| C2 | Bahadori et al., "Effects of Chromium Picolinate on Insulin Levels and Glucose Control in Obese Patients with Type - II Diabetes Mellitus," <i>Diabetes</i> , Abstract Book, 59 th Scientific Sessions, pp. A349 (1999) |
| C3 | ChromeMate: Research Summary (1993) |
| C4 | Salonen et al., "Increased risk of non-insulin dependent diabetes mellitus at low plasma vitamin E concentrations: a four year follow up study in men" <i>BMJ</i> 311, pp. 1124-1127 (1995) |
| C5 | Diabetes Pro Health Inc., "Introducing A Nutritional Supplement Specifically Formulated For Adults With Diabetes & Pre-Diabetes" (1997) |
| C6 | Verma et al., "Metformin improves cardiac function in isolated streptozotocin-diabetic rat hearts," <i>American Journal of Physiology</i> , (1994) |
| C7 | Haupt et al., "Metformin and its role in the management of type-2-diabetes," <i>Medizinische Klinik</i> , Munich, (1997) |
| C8 | Anderson et al., "Elevated intakes of supplemental chromium improve glucose and insulin variables in individuals with type 2 diabetes," <i>Diabetes</i> , Vol. 46, No. 11, pp. 1786-1791 (1997) |
| C9 | Ziegler et al., "Treatment of symptomatic diabetic peripheral neuropathy with the anti-oxidant α -lipoic acid: A 3-week multicenter randomized controlled trial (Aladin Study)," <i>Diabetes-Forschungsinstitut</i> , (1995) |
| C10 | Pote et al., "An antiatherogenic role for folic acid in experimental diabetes," <i>Journal of Clinical Biochemistry and Nutrition</i> , Vol. 18(3), pp. 157-164 (1995) |
| C11 | Mark et al., "Hypoglycemic effects of the novel antidiabetic agent repaglinide in rats and dogs," <i>British Journal of Pharmacology</i> , Vol. 121(8), pp. 15497-1604 (1997) |

| | |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE